THE SUPPLY OF MACHINERY (SAFETY) REGULATIONS 2008

GUIDELINES ON THE APPOINTMENT OF UK NOTIFIED BODIES TO UNDERTAKE INSPECTION AND CERTIFICATION FOR THE PURPOSES OF THE CONFORMITY ASSESSMENT PROCEDURES IN THE UK REGULATIONS

FEBRUARY 2009

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GUIDELINES ON THE APPOINTMENT OF UK NOTIFIED BODIES

ISSUED BY THE DEPARTMENT FOR BUSINESS, INNOVATION AND SKILLS (BIS) ON BEHALF OF THE SECRETARY OF STATE FOR BIS

1. INTRODUCTION

1.1. These guidelines describe the requirements applying in the United Kingdom for the assessment and appointment of Notified Bodies under the Supply of Machinery (Safety) Regulations 2008 (S.I. 2008/1597), which implement the provisions of the EC Machinery Directive (2006/42/EC) in UK law. These regulations replace in their entirety the Supply of Machinery (Safety) Regulations 1992 (as amended) which implemented the previous Machinery directive (98/37/EC) on the coming into force date for directive 2006/42/EC of 29 December 2009. Notified Bodies are appointed under and operate according to the law which transposes the provisions of the Directive and any appointments under the old set of regulations will terminate automatically on that date. The text of the Directive was adopted by the European Parliament and the Council on 25 April 2006 and published in the Official Journal No. L 157 of 9 June 2006, p.24. The Directive applies in the European Economic Area (EEA).

1.2. The UK Supply of Machinery (Safety) Regulations 2008 apply to 'machinery' which falls within the definition in Regulation 4. There is a specific list of products which may require third party examination in parts 4 and 5, Schedule 2 to the Supply of Machinery (Safety) Regulations (Annex IV and V of the Directive). In these cases, if a transposed harmonised standard has not been used in order to ensure compliance for the product, a third party is required to examine the product and to issue a type examination certificate before it can be placed on the market in the EEA. Alternatively a Full Quality Assurance Assessment is now available in these circumstances if a manufacturer so wishes.

1.3. The conformity assessment procedures under the Regulations consist of self-certification by the manufacturer of each product either directly in accordance with the technical requirements set out in the Regulations or against a specific transposed harmonised European Standard (EN), or series of standards, which then gives that product a presumption of conformity with the relevant essential health and safety requirements of the Regulations. In these circumstances a manufacturer can self-certify his product and if appropriate affix the CE marking. If, however, the product is listed in part 4 of Schedule 2 to the Regulations, third party assessment is required, if the product is not wholly manufactured in accordance with transposed harmonised standards. Where such third party assessment is required, the Notified Body will perform the EC type examination and issue a certificate to the manufacturer once it has been assessed as being in conformity with the requirements of the Regulations as

amended or will carry out the Full Quality Assurance procedure now available under Part 10 of Schedule 2.

1.4. Third party assessment requires the involvement of Notified Bodies in the type approval process or Full Quality Assurance as outlined above. Subject to paragraph 7 (below), these are appointed by member/EEA States. In the United Kingdom, they are appointed under regulations 16-18 of the Supply of Machinery (Safety) Regulations 2008. These organisations, once assessed for their competence and appointed by the Secretary of State, are then notified to the European Commission and become "Notified Bodies". The scope of products within Schedule 2 to the Regulations which a Notified Body is authorised to assess will be published and will also be specified in the letter of appointment. The Secretary of State for Business, Innovation and Skills at present has the responsibility for appointing Notified Bodies in the United Kingdom to carry out the functions referred to above and for notifying the appointments to the European Commission and other member/EEA States.

2. CRITERIA, APPLICATION AND APPOINTMENT

2.1. An organisation wishing to be appointed as a notified body in the United Kingdom will need to be able to undertake assessments in accordance with the relevant provisions of the Regulations which implement either Annex IX or X or both of the Machinery Directive (reproduced here as Appendices I and 2) and meet the minimum criteria set out in Annex XI of the Directive (reproduced here as Appendix 3 to these Guidelines). It should, however, be noted that meeting the minimum criteria for appointment will not automatically lead to such an appointment as this remains at the discretion of the Secretary of State. The requirements set out in paragraph 2.7 below must also be fulfilled. Finally reference should also be made to paragraph 3.14 regarding insurance arrangements.

2.2. Applicants will be required in the first instance, to make an application (for assessment) to the United Kingdom Accreditation Service (UKAS) which will undertake an assessment of the applicant against the criteria and report to the Secretary of State. Applications should be submitted using UKAS form AC6. The scope of any appointment will be defined by reference to the specific products set out in part 4 of Schedule 2 to the Supply of Machinery (Safety) Regulations 2008 and applicants should indicate the particular product(s) (if not all) in respect of which they wish to be appointed. UKAS will quote and charge applicants against its standard scales of charges for its assessment activities under the provisions of these guidelines. UKAS has established procedures to handle complaints or appeals associated with its assessment activities.

2.3. At the same time as it submits its application for assessment to UKAS, the applicant will be required to send a copy to BIS. This will represent the formal application to the Secretary of State for appointment.

2.4. Once UKAS has submitted its report, the Secretary of State will then make a decision on appointment on the basis of all of the evidence. If satisfied that the applicant is fit for appointment under the Supply of Machinery (Safety) Regulations 2008 (and any subsequent amendments), the Secretary of State will issue a letter of appointment.

2.5. The precise terms of appointment will be set out in the individual letters of appointment, but they will include conditions that the applicant agrees:

- to take part in co-ordination activities at both UK and European level;

- to surveillance annually or at whatever intervals are thought appropriate by BIS (newly appointed Notified Bodies may be required to undergo an initial surveillance after 6 months);

- to a full reassessment every four years or at whatever intervals are thought appropriate by BIS.

Once acceptance of the conditions of the letter of appointment has been received, receipt of that acceptance will be confirmed and BIS will notify the European Commission and the other member/EEA States of the appointment.

2.6. Reassessment and surveillance will be carried out on behalf of the Secretary of State, normally by UKAS. A report on the reassessment and surveillance will be sent to the Secretary of State. Reassessment and surveillance may also be carried out by the Secretary of State. UKAS will advise BIS of the outcome of annual surveillance, four yearly re-assessment and any other necessary monitoring in intervening periods of Notified Bodies in order for BIS to take any necessary decisions about the continuation of a Notified Body's appointment. The information provided by UKAS to BIS will include supporting documentation such as a copy of the assessor's visit report, details of identified deficiencies and any agreed remedial action.

To be eligible for appointment as a United Kingdom Notified Body for the purposes of the Regulations as amended, an applicant must be a legal entity in the United Kingdom and carry out its assessment functions within the jurisdiction of the United Kingdom. It may, where necessary, conduct tests, or have tests conducted on its behalf, outside the jurisdiction of the United Kingdom.

2.7. Notified Bodies should ensure that they do not unreasonably restrict the access of manufacturers of products within the scope of the Regulations to their services. They must not place undue financial or other conditions upon such manufacturers. The procedures under which a Notified Body operates must be administered in a non-discriminatory manner.

3 MEETING THE CRITERIA

Accreditation

3.1 Accreditation to the appropriate scope of one, or more, of the relevant EN 45000 and ISO 17000 series of standards, which contain requirements for bodies issuing certificates, performing inspections or conducting tests, may be used as the basis for demonstrating conformity with the criteria set out in Appendices 1, 2 and 3. Although accreditation to one of the relevant EN 45000 and ISO 17000 series standards is encouraged, it is not mandatory and the relevant criteria may be satisfied in other ways. Applicants which are not accredited will normally be assessed by UKAS to the relevant requirements of the appropriate EN 45000 and 17000 standards and will need to demonstrate equivalent levels of ability in terms of competence, resources, organisational arrangements, policies and all other relevant matters.

3.2 All applicants, whether accredited to one of the EN 45000 or ISO 17000 series of standards or not, will need to meet the additional requirements set out in these guidelines which may change from time to time. In particular, they will need to demonstrate:

- a thorough technical understanding of the products for which appointment is sought;

- the ability to undertake the conformity assessment activities laid down in the Regulations in respect of which they seek appointment; and

- a thorough knowledge of the Machinery Directive and the implementing Regulations.

- Applicants wishing to provide the Full Quality Assurance Module in accordance with Annex X should consider the requirements of ISO 19011 when defining the requirements for competence of assessors.

3.3 As indicated in paragraph 3.2 (above), applicants will therefore need to state for which products specified in Schedule 2 to the Regulations they wish to be appointed. The scope of assessment and subsequent appointment will be determined by reference to the categories of product listed in Schedule 2 to those Regulations (Annex IV of the Machinery Directive - see Appendix 3). Applicants will be required to demonstrate the capability fully to undertake the EC type examination in accordance with the requirements of the Regulations (as amended) and satisfy the minimum criteria as shown in Appendix 2 to these Guidelines.

3.4 ISO 17020 is the basic standard for assessing the suitability of applicants wishing to become Notified Bodies to carry out type examinations under the Regulations. Assessment of an applicant will also be related to its ability to understand the Essential Health and Safety Requirements (EHSRs) and other relevant provisions of

the Machinery Directive and the implementing Regulations relevant to its proposed scope of approval and to undertake the conformity assessment duties of a notified body in the required manner.

3.5 ISO 17021 is the basic standard for assessing the suitability of applicants wishing to become Notified Bodies to carry out assessment of Quality Systems. Assessment of an applicant will also be related to its ability to understand the Essential Health and Safety Requirements (EHSRs) and other relevant provisions of the Machinery Directive and the implementing Regulations relevant to its proposed scope of approval and to undertake the Full Quality Assessment duties of a notified body in the required manner.

3.6 All applicants will need to be able to demonstrate their professional ability and a necessary level of understanding of the Machinery Directive and of the implementing Regulations to be able to determine whether products offered for assessment satisfy the EHSRs and the other relevant provisions.

Harmonised Standards

3.7 The Machinery Directive also defines the role of harmonised standards, which are produced in response to a mandate from the European Commission to the European standards organisation, the Comite European de Normalisation (CEN) and the European Committee for Electrotechnical Standardization (CENELEC). Products within the scope of the Machinery Directive/implementing Regulations produced in accordance with such standards will enjoy a presumption of conformity with the relevant EHSRs (set out in Schedule 2 to the Regulations) Under the appropriate conformity assessment procedures, applicants will need to be able to examine or inspect against the EHSRs and other relevant provisions directly. They will also need to be able to inspect against the CEN and CENELEC standards.

3.8 Where an applicant operates its own testing facilities or utilises those of a manufacturer, these, and the associated activities, will need to conform to the relevant requirements of EN 17025 (General criteria for the operation of testing and calibration laboratories) though accreditation is not mandatory. Where testing is performed on its behalf by a manufacturer or by a subcontractor, the applicant will need to ensure that that organisation is capable of carrying out the tasks effectively and meets the relevant requirements of EN 17025 although accreditation is not mandatory.

3.9 Where an applicant operates its own inspection facilities or utilises those of a manufacturer, these, and the associated activities, will need to conform to the relevant requirements of EN 17020 (General criteria for the operation of various types of bodies performing inspection) though accreditation is not mandatory. Although a Notified Body should normally carry out inspections which it contracts to undertake, where elements of the inspection will be performed on its behalf by a manufacturer or by a subcontractor, the applicant will need to ensure that that organisation is capable

of carrying out the tasks effectively and meets the relevant requirements of EN 17020 although accreditation is not mandatory.

Sub-Contracting

3.10 Where an applicant wishes to sub-contract testing, the Quality Manual of the applicant will need to describe the procedures to be followed by the applicant to ensure compliance by the sub-contractors with the relevant requirements and to demonstrate that the sub-contractor is competent to carry out the task for which it has been engaged. Such competence will include, but is not limited to, the ability fully to conform to the requirements that are placed on the applicant itself in respect of the task contained within the subcontract. The applicant will need to maintain documented procedures for the assessment and monitoring of sub-contractors, and a list of sub-contractors and the facilities used by them to carry out work packages on behalf of the applicant. The list will need to form part of the Register specified in the next paragraph.

3.11 An applicant will need to have fully documented agreements with its sub-contractors. A Register of all sub-contractors which may be used by the applicant will need to be maintained; the Quality Manual will either contain the Register or will state where the Register is to be found. The agreements and the Register will need to be available for scrutiny at any reasonable time on request by the Secretary of State or such other person as may be appointed on behalf of the Secretary of State for that purpose.

3.12 A Notified Body will at all times be responsible for ensuring that the conformity assessment is carried out in accordance with the requirements of the implementing Regulations.

3.13 An applicant will need to have a Quality System, usually specified in a Quality Manual and associated documented operational procedures, appropriate to the conformity assessment modules and types of product which it wishes to certify. The Quality System will need to ensure that all of the relevant requirements of the appropriate standards in the EN 17000 and 45000 series are met plus any further requirements for appointment and operation as a Notified Body.

3.14 All applicants will be required to demonstrate that they have adequate public liability and professional indemnity insurance for the activities they wish to carry out. Evidence of this should be submitted to UKAS and to BIS at the point at which a body makes an application to be appointed as a Notified Body. Thereafter, the Notified Body should make available to UKAS evidence of insurance at each annual surveillance undertaken by UKAS. Such cover should extend to the whole of the Community, the European Economic Area (EEA), or, if the applicant intends to carry out work under the Machinery Directive outside these areas; world-wide. The Secretary of State will not in relation to any case or circumstance cover a Notified Body’s liability.

3.15 A Notified Body will be required to inform the Secretary of State for Business, Innovation and Skills and UKAS immediately of any changes within itself which, in any way, affect its ability to carry out the duties within the authorised scope to the declared procedures. This includes any change in its status.

4 DUTIES OF NOTIFIED BODIES

4.1 It will be the duty of a Notified Body to assess the conformity of the products or quality systems, which fall within the scope of its appointment, against the requirements of the Supply of Machinery (Safety) Regulations 2008. When a Notified Body assesses products as being in conformity with those Regulations, it will be required to issue the appropriate conformity assessment documentation as specified in the Regulations. This would include a type examination or quality assurance certificate stating that the product concerned complies with the terms of the Directive which apply to it and has been assessed as such.

4.2 An applicant will be required to have documented procedures covering all aspects of its work relating to the conformity assessment activities for which it seeks approval. On behalf of the Secretary of State, an assessment will be made of the adequacy of the internal organisation and the procedures adopted to give confidence in the quality of the applicant's services. Where judgements or interpretation of a standard or requirement are implicit or explicit in a decision to grant or withhold certification, the applicant will be required to have procedures for achieving consistency. Guidance for achieving wider national and European agreement on interpretation and application of the Machinery Directive and the implementing Regulations can be sought from BIS, or through the national and European fora already in place for the exchange of views and discussion of interpretative issues in which prospective applicants are expected to fully participate.

4.3 A Notified Body will be required to maintain an up to date record of any certification which it has issued, and to whom it has been issued. The records will need to be made available on request to the Secretary of State for Business, Innovation and Skills, or such other person as may be authorised by the Secretary of State for Business, Innovation and Skills.

5 MISUSE OF CERTIFICATES AND CONFORMITY NUMBERS

5.1 The Quality Manual should state the Notified Body's policy and procedure for controlling the use of its certificates and conformity numbers. Incorrect references to the certification system or misleading use of information found in advertisements, catalogues etc. will be dealt with by suitable means including corrective action, publication of the transgression and, if necessary, legal action.

5.2 A Notified Body will need to have documented procedures for the control and use of its identification number complete with guidelines on action to be taken in cases of misuse. The procedures will need to be contained or referenced within the Quality Manual.

6 MUTUAL RECOGNITION AGREEMENTS

6.1 Applicants should note that the European Community aims to reach Mutual Recognition Agreements (MRAs) with key trading partners. Under these agreements, EC Notified Bodies may be eligible to perform conformity assessments as required by the third country's laws and, similarly, those trading partners' equivalents to Notified Bodies may be eligible for appointment to perform conformity assessments under EC Directives. If an applicant organisation wishes to be considered for appointment under MRAs, it should inform BIS.

7 CONTACT POINTS

7.1 Contact addresses are:

Peter Baxter-Ludlow / Graham Payne
Department for Business, Innovation and Skills
Environmental & Technical Regulation Directorate
1 Victoria Street
London, SW1H 0ET

Tel: 0207-215 1453 / 0207-215 0923
Fax: 0207-215 2635 / 0207-215 2635

Lorraine Turner (or your usual accreditation manager)
United Kingdom Accreditation Service
21 - 47 High Street
Feltham
Middlesex, TW13 4UN

Tel: 0208 - 917 8400
Fax: 0208 - 917 8500

8 SOURCES OF RELEVANT DOCUMENTS

8.1 Copies of the Machinery Directive and the Supply of Machinery (Safety) Regulations 2008 may be obtained from:

The Stationery Office Ltd
PO Box 29
Norwich, NR3 IGN

Tel: 0870 600 5522
Fax: 0870 600 5533
Email: customer.services@tso.co.uk
Textphone 0870 240 3701

or from **Euro Info Centres**

8.2 Information on the EN 17000 and EN 45000 series of standards and the harmonised standards is available from:

BSI British Standards
389 Chiswick High Road
London, W4 4AL

Tel: 0208-996 9001
Fax: 0208-996 7001
Web: http://www.bsi.group.com

Appendix I: Extract from the EC Machinery Directive 2006/42/EC

ANNEX IX

EC TYPE-EXAMINATION

EC type-examination is the procedure whereby a notified body ascertains and certifies that a representative model of machinery referred to in Annex IV (hereafter named the type) satisfies the provisions of this Directive.

1. The manufacturer or his authorised representative must, for each type, draw up the technical file referred to in Annex VII, part A.

2. For each type, the application for an EC type-examination shall be submitted by the manufacturer or his authorised representative to a notified body of his choice.

   The application shall include:

   — the name and address of the manufacturer and, where appropriate, his authorised representative,

   — a written declaration that the application has not been submitted to another notified body,

   — the technical file.

   Moreover, the applicant shall place at the disposal of the notified body a sample of the type. The notified body may ask for further samples if the test programme so requires.

3. The notified body shall:

3.1. examine the technical file, check that the type was manufactured in accordance with it and establish which elements have been designed in accordance with the relevant provisions of the standards referred to in Article 7(2), and those elements whose design is not based on the relevant provisions of those standards;

3.2. carry out or have carried out appropriate inspections, measurements and tests to ascertain whether the solutions adopted satisfy the essential health and safety requirements of this Directive, where the standards referred to in Article 7(2) were not applied;

3.3. where harmonised standards referred to in Article 7(2) were used, carry out or have carried out appropriate inspections, measurements and tests to verify that those standards were actually applied;

3.4. agree with the applicant as to the place where the check that the type was manufactured in accordance with the examined technical file and the necessary inspections, measurements and tests will be carried out.

4. If the type satisfies the provisions of this Directive, the notified body shall issue the applicant with an EC type-examination certificate. The certificate shall include the name and address of the manufacturer and his authorised representative, the data necessary for identifying the approved type, the conclusions of the examination and the conditions to which its issue may be subject.

   The manufacturer and the notified body shall retain a copy of this certificate, the technical file and all relevant documents for a period of 15 years from the date of issue of the certificate.

5. If the type does not satisfy the provisions of this Directive, the notified body shall refuse to issue the applicant with an EC type-examination certificate, giving detailed reasons for its refusal. It shall inform the applicant, the other notified bodies and the Member State which notified it. An appeal procedure must be available.

6. The applicant shall inform the notified body which retains the technical file relating to the EC type-examination certificate of all modifications to the approved type. The notified body shall examine these modifications and shall then either confirm the validity of the existing EC type-examination certificate or issue a new one if the modifications are liable to compromise conformity with the essential health and safety requirements or the intended working conditions of the type.

7. The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EC type-examination certificates. On reasoned request, the Commission and the Member States may obtain a copy of the technical file and the results of the examinations carried out by the notified body.

8. Files and correspondence referring to the EC type-examination procedures shall be written in the official Community language(s) of the Member State where the notified body is established or in any other official Community language acceptable to the notified body.

9. Validity of the EC type-examination certificate

9.1. The notified body has the ongoing responsibility of ensuring that the EC type-examination certificate remains valid. It shall inform the manufacturer of any major changes which would have an implication on the validity of the certificate. The notified body shall withdraw certificates which are no longer valid.

9.2. The manufacturer of the machinery concerned has the ongoing responsibility of ensuring that the said machinery meets the corresponding state of the art.

9.3. The manufacturer shall request from the notified body the review of the validity of the EC type-examination certificate every five years.

If the notified body finds that the certificate remains valid, taking into account the state of the art, it shall renew the certificate for a further five years.
The manufacturer and the notified body shall retain a copy of this certificate, of the technical file and of all the relevant documents for a period of 15 years from the date of issue of the certificate.

9.4. In the event that the validity of the EC-type examination certificate is not renewed, the manufacturer shall cease the placing on the market of the machinery concerned.

Appendix 2 Extract from the EC Machinery Directive 2006/42/EC

ANNEX X

FULL QUALITY ASSURANCE

This Annex describes the conformity assessment of machinery referred to in Annex IV, manufactured using a full quality assurance system, and the procedure whereby a notified body assesses and approves the quality system and monitors its application.

1. The manufacturer must operate an approved quality system for design, manufacture, final inspection and testing, as specified in point 2, and shall be subject to the surveillance referred to in point 3.

2. Quality system

2.1. The manufacturer or his authorised representative shall lodge an application for assessment of his quality system to a notified body of his choice.

The application shall contain:

— the name and address of the manufacturer and, where appropriate, his authorised representative,

— the places of design, manufacture, inspection, testing and storage of the machinery,

— the technical file described in Annex VII, Part A, for one model of each category of machinery referred to in Annex IV which he intends to manufacture,

— the documentation on the quality system,

— a written declaration that the application has not been submitted to another notified body.

2.2. The quality system must ensure conformity of the machinery with the provisions of this Directive. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner, in the form of measures, procedures and written instructions. The documentation on the quality system must permit a uniform interpretation of the procedural and quality measures, such as quality programmes, plans, manuals and records.

It must contain, in particular, an adequate description of:

— the quality objectives, the organisational structure, and the responsibilities and powers of the management with regard to the design and quality of the machinery,

— the technical design specifications, including standards that will be applied and, where the standards referred to in Article 7(2) are not applied in full, the means that will be used to ensure that the essential health and safety requirements of this Directive are fulfilled,

— the design inspection and design verification techniques, processes and systematic actions that will be used when designing machinery covered by this Directive,

— the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,

— the inspections and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,

— the quality records, such as inspection reports and test data, calibration data, and reports on the qualifications of the personnel concerned,

— the means of monitoring the achievement of the required design and quality of the machinery, as well as the effective operation of the quality system.

2.3. The notified body shall assess the quality system to determine whether it satisfies the requirements of point 2.2.

The elements of the quality system which conform to the relevant harmonised standard shall be presumed to conform to the corresponding requirements referred to in point 2.2.

The team of auditors must have at least one member who is experienced in the assessment of the technology of the machinery. The assessment procedure shall include an inspection to be carried out at the manufacturer's premises. During the assessment, the team of auditors shall carry out a review of the technical files referred to in point 2.1, second paragraph, third indent to ensure their compliance with the relevant health and safety requirements.

The manufacturer or his authorised representative shall be notified of the decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision. An appeal procedure must be available.

2.4. The manufacturer shall undertake to fulfil the obligations arising from the quality system as approved and to ensure that it remains appropriate and effective.

The manufacturer or his authorised representative shall inform the notified body which approved the quality system of any planned change to it.

The notified body shall evaluate the proposed changes and decide whether the modified quality assurance system will continue to satisfy the requirements referred to in point 2.2, or whether a re-assessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3. Surveillance under the responsibility of the notified body

3.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

3.2. The manufacturer shall, for inspection purposes, allow the notified body access to the places of design, manufacture, inspection, testing and storage, and shall provide it with all necessary information, such as:

— the documentation concerning the quality system,

— the quality records provided for in that part of the quality system concerned with design, such as the results of analyses, calculations, tests, etc.,

— the quality records provided for in that part of the quality system concerned with manufacture, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.

3.3. The notified body shall conduct periodic audits to make sure that the manufacturer is maintaining and applying the quality system; it shall provide the manufacturer with an audit report. The frequency of the periodic audits shall be such that a full reassessment is carried out every three years.

3.4. Moreover, the notified body may pay the manufacturer unannounced visits. The need for these additional visits and their frequency will be determined on the basis of a visit monitoring system managed by the notified body. In particular, the following factors will be taken into account in the visits monitoring system:

— the results of previous surveillance visits,

— the need to monitor remedial measures,

— where appropriate, special conditions attaching to approval of the system,

— significant modifications in the organisation of the manufacturing process, measures or techniques.

On the occasion of such visits, the notified body may, if necessary, carry out tests or have them carried out in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if a test was carried out, with a test report.

4. The manufacturer or his authorised representative shall keep available for the national authorities, for a period of ten years from the last date of manufacture:
— the documentation referred to in point 2.1,

— the decisions and reports of the notified body referred to in point 2.4, third and fourth subparagraphs, and in points 3.3 and 3.4.

Appendix 3 Extract from the EC Machinery Directive 2006/42/EC

ANNEX XI

Minimum criteria to be taken into account by Member States for the notification of bodies

1. The body, its director and the staff responsible for carrying out the verification tests shall not be the designer, manufacturer, supplier or installer of machines which they inspect, nor the authorised representative of any of these parties. They shall not become involved, either directly or as authorised representatives, in the design, construction, marketing or maintenance of the machines. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.

2. The body and its staff shall carry out the verification tests with the highest degree of professional integrity and technical competence and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.

3. For each category of machinery for which it is notified, the body must possess personnel with technical knowledge and sufficient and appropriate experience to perform a conformity assessment. It must have the means necessary to complete the technical and administrative tasks connected with implementation of the checks in an appropriate manner; it must also have access to the equipment necessary for the exceptional checks.

4. The staff responsible for inspection shall have:

   — sound technical and vocational training,

   — satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests,

   — the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.

5. The impartiality of inspection staff shall be guaranteed. Their remuneration shall not depend on the number of tests carried out or on the results of such tests.

6. The body shall take out liability insurance unless its liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the tests.

7. The staff of the body shall be bound to observe professional secrecy with regard to all information obtained in carrying out its tasks (except vis-à-vis the competent administrative authorities of the State in which its activities are carried out) under this Directive or any provision of national law giving effect to it.

8. Notified bodies shall participate in coordination activities. They shall also take part directly or be represented in European standardisation, or ensure that they know the situation in respect of relevant standards.

9. Member States may take all necessary measures they regard as necessary in order to ensure that, in the event of cessation of the activities of a notified body, the files of its customers are sent to another body or are made available to the Member State which has notified it.

Appendix 4 List of products covered by Schedule 2 to the Supply of Machinery (Safety) Regulations 2008 (Annex IV of the Machinery Directive 2006/42/EC)

Machinery

1 Circular saws (single- or multi-blade) for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:

1.1 sawing machinery with fixed blade(s) during cutting, having a fixed bed or support with manual feed of the workpiece or with a demountable power feed;

1.2 sawing machinery with fixed blade(s) during cutting, having a manually operated reciprocating saw-bench or carriage;

1.3 sawing machinery with fixed blade(s) during cutting, having a built-in mechanical feed device for the workpieces, with manual loading and/or unloading;

1.4 sawing machinery with movable blade(s) during cutting, having mechanical movement of the blade, with manual loading and/or unloading.

2 Hand-fed surface planing machinery for woodworking.

3 Thicknessers for one-side dressing having a built-in mechanical feed device, with manual loading and/or unloading for woodworking.

4 Band-saws with manual loading and/or unloading for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:

4.1 sawing machinery with fixed blade(s) during cutting, having a fixed or reciprocating-movement bed or support for the workpiece;

4.2 sawing machinery with blade(s) assembled on a carriage with reciprocating motion.

5 Combined machinery of the types referred to in points 1 to 4 and point 7 of this Annex, for working with wood and material with similar physical characteristics.

6 Hand-fed tenoning machinery with several tool holders for woodworking.

7 Hand-fed vertical spindle moulding machinery for working with wood and material with similar physical characteristics.

8 Portable chainsaws for woodworking.

9 Presses, including press-brakes, for the cold working of metals, with manual loading and/or unloading, whose movable working parts may have a travel exceeding 6 mm and a speed exceeding 30 mm/s.

10 Injection or compression plastics-moulding machinery with manual loading or unloading.

11 Injection or compression rubber-moulding machinery with manual loading or unloading.

12 Machinery for underground working of the following types:

12.1 locomotives and brake-vans;

12.2 hydraulic-powered roof supports.

13 Manually loaded trucks for the collection of household refuse incorporating a compression mechanism.

14 Removable mechanical transmission devices including their guards.

15 Guards for removable mechanical transmission devices.

16 Vehicle servicing lifts.

17 Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than three metres.

18 Portable cartridge-operated fixing and other impact machinery.

19 Protective devices designed to detect the presence of persons.

20 Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9, 10 and 11 of this Annex.

21 Logic units to ensure safety functions.

22 Roll-over protective structures (ROPS).

23 Falling-object protective structures (FOPS).